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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,831

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Berta Kotar-Jordan

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08/26/2010

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

08/26/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,831	Applicant(s) KOTAR-JORDAN ET AL.	
	Examiner Brenda L. Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-22, 24 and 26-32 is/are allowed.
- 6) ☒ Claim(s) 23 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-24 and 26-33 are pending in the application.

This action is in response to applicants' amendment filed June 11, 2010. Claim 23 has been amended and claim 33 is newly added.

Response to Amendment

Applicant's amendments filed June 11, 2010 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, second paragraph rejection of claim 23 labeled paragraph 1d) maintained in the last office action, the applicant's arguments have been fully considered, however they were not found persuasive.

d) The applicants stated that the terms of "hydrate" and "solvate", they are commonly used and understood in the art. That which the applicants have considered to be well known in the art does not set forth that which the applicants consider to be the invention and also is open to an even broader interpretation. Thus the applicants have not set forth the metes and bounds of the claim. You can force an alcohol to form an ester, you can force an amine to form a salt, but you cannot force a compound to form a hydrate and/or a solvate. These compounds do not possess the property of forming hydrates and/or solvates other than the isopropanol/water solvate; there is no evidence that such compounds even exist. Thus, this is a circumstance where the "specification is evidence of its own inadequacy" (*In re Rainer*, 377 F.2d 1006, 1012, 153 USPQ 802, 807). These cannot be simply willed into existence. As was stated in

Morton International Inc. v. Cardinal Chemical Co., 28 USPQ2d 1190 “The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However, the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist.” The same circumstance appears to be true here: there is no evidence that hydrates or solvates other than the isopropanol/water solvate, of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that hydrates and other solvates can be made, or limit the claims accordingly. *In re Marzocchi*, 169 USPQ 367, 369 an exception for when “there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.”

Claim 23 and newly added claim 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

2. The applicant's amendments and arguments are sufficient to overcome the obviousness-type double patenting rejection labeled paragraph 3) of the last office action, which is hereby **withdrawn**.
3. With regards to the 35 U.S.C. § 112, first paragraph rejection of claim 23 labeled paragraph 4) in the last office action, the applicant's arguments have been fully

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considered, however they were not found persuasive. The applicants' stated that "the present application provides specific examples of making a solvate of olanzapine using the isopropanol/water mixed solvate of olanzapine of claim 1 as the starting material".

Solvates are crystalline organic solids made up of molecules that are packed or ordered in a specific arrangement. These molecules are held together by relatively weak forces, such as hydrogen bonding and van der Waals interactions. The arrangement of the molecules is defined by a unit cell, which is the smallest repeating unit of a crystal.

These different arrangements determine the crystal form of the material and...include solvates, hydrates.... The solvent co-crystallizes with the compound in a specific arrangement. X-ray diffraction techniques and infrared spectroscopy, among others, are the two most common instruments used to help characterize solvates. Different solvents solvate compounds by different means, e.g. hydrogen bonding, pi-pi stacking, van der Waals interactions, etc. These different interactions form different solvates and thus different crystals. The crystal form used in development is important based on possible manufacturability, solubility, bioavailability and stability differences between the different solid forms.

Newly added Claim 33 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other forms, does not reasonably provide enablement for solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims, for reasons of record and stated above.

Allowable Subject Matter

4. Claims 1-22, 24 and 26-32 are allowed. None of the prior art of record or a search in the pertinent art area teaches the isopropanol/water mixed solvate of olanzapine or the process of preparing form I olanzapine wherein the olanzapine form I is crystallized or precipitated from a liquid medium which medium is present in a container wherein the surfaces of the container contacting the medium are comprising at least one polymer.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624